



IFW

Docket No.: 5374-0101PUS1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Shingo HIRAMATSU et al.

Application No.: 10/585,742

Confirmation No.: N/A

Filed: July 12, 2006

Art Unit: N/A

For: SILK THREAD CONTAINING SPIDER  
THREAD PROTEIN AND SILK WORM  
PRODUCING THE SILK THREAD

Examiner: Not Yet Assigned

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on July 12, 2006, attached hereto is an English Translation of the International Preliminary Report on Patentability issued by the International Bureau on behalf of the International Searching Authority. Please make this document of record for the above-identified application

Application No.: 10/585,742

Docket No.: 5374-0101PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: November 22, 2006

Respectfully submitted,

By 

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Attachment(s)

## PATENT COOPERATION TREATY

PCT/JP2005/000619



## PCT

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

From the INTERNATIONAL BUREAU

18.9.-7

To:

TAKAGI, Chiyoshi  
Subaru Patent Office, Kojimachi Koyo Bldg.,  
10, Kojimachi 1-chome, Chiyoda-ku, Tokyo  
1020083  
JAPON

Date of mailing (day/month/year) 31 August 2006 (31.08.2006)	
Applicant's or agent's file reference FP1085SUBARU	IMPORTANT NOTIFICATION
International application No. PCT/JP2005/000619	International filing date (day/month/year) 12 January 2005 (12.01.2005)
Applicant TORAY INDUSTRIES, INC. et al	

## 1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP1085SUBARU	FOR FURTHER ACTION		See item 4 below
International application No. PCT/JP2005/000619	International filing date ( <i>day/month/year</i> ) 12 January 2005 (12.01.2005)	Priority date ( <i>day/month/year</i> ) 13 January 2004 (13.01.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant TORAY INDUSTRIES, INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland		Date of issuance of this report 22 August 2006 (22.08.2006)
Facsimile No. +41 22 338 82 70		Authorized officer Yoshiko Kuwahara
Form PCT/IB/373 (January 2004)		e-mail: pt07@wipo.int

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**FP1085SUBARU**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2005/000619**

International filing date (day/month/year)

**12.01.2005**

Priority date (day/month/year)

**13.01.2004**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**TORAY INDUSTRIES, INC.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/000619

Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language  
\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☒ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/000619

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	4, 5, 9-17, 20-22, 26	YES
	Claims	1-3, 6-8, 18, 19, 23-25	NO
Inventive step (IS)	Claims		YES
	Claims	1-26	NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims		NO
2. Citations and explanations:			
<p>Document 1: US, 2002-0137211, A (Chengdu Tianyou Development Co., Ltd.), 4 October, 2002 (04.10.02), &amp; CN, 1362520, A</p> <p>Document 2: "Kumo no Ito o Kaiko ni Hakaseru Kenkyu (Idenshi Targeting ni yoru Kasan Fibroin Idenshi no Kaizo)." (Masao Nakagaki et al.), Ministry of Education, Culture, Sports, Science and Technology Kagaku Kenkyuhui Hojokin (COE Keisei Kiso Kenkyuhui), 'Senshin Sen'i Gijutsu Kagaku ni Kansuru Kenkyu' (Kadai Bango 10CE2003) Seika Hokokusho VIII, Heisei 13 Nendo Seika Hokokusho, 14 March, 2002 (14.03.02), page 83</p> <p>Document 3: "Idenshi Kumikae Kaiko to Shinsen'i," (Toshiki Tamura), Kobunshi (2003), Vol. 52, No. 11, pages 822 to 825</p> <p>Document 4: US, 6018030, A (Protein Polymer Technologies Inc.), 25 January, 2000 (25.01.00) (Family: none)</p> <p>Document 5: WO, 94-29450, A (Du Pont De Nemours &amp; Co. E I), 22 December, 1994 (22.12.94), &amp; EP, 707645, A, &amp; JP, 8-511426, A, &amp; US, 6268169, B</p> <p>Document 6: "Molecular biology of spider silk," (Stefan Winkler et al.), Review in Molecular Biotechnology (2000), Vol. 74, No. 2, pages 85 to 93</p> <p>Claims 1-3, 6-8, 18, 19 and 23-25</p> <p>The subject matters of claims 1-3, 6-8, 18, 19 and 23-25 do not appear to be novel in view of document 1.</p> <p>Document 1 describes a transgenic silkworm into which a gene is transferred, which encodes a spider thread protein between a promoter part and a C-end part of a fibroin L-chain protein. Document 1 also describes that a gene is transferred with a vector encoding transposase and a piggyBac vector and that silk containing spider thread silk is obtained.</p> <p>Claim 26</p> <p>The subject matter of claim 26 does not appear to involve an inventive step in view of document 1.</p> <p>When obtaining new silk, there is not found any difficulty in manufacturing textile fabrics using its thread.</p> <p>Claims 21 and 22</p> <p>The subject matters of claims 21 and 22 do not appear to be novel in view of document 2.</p>			

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/000619

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

Document 2 describes a study on making a silkworm spew out a spider thread. According to the said study, a silkworm is inoculated with a vector into which a gene of a spider thread protein that is inserted in frame among the homologous arrays of a fibroin H-chain gene and a GFP gene are transferred.

Claims 1, 2, 6-8, 19 and 25

The subject matters of claims 1, 2, 6-8, 19 and 25 do not appear to be novel in view of document 3.

Document 3 describes as follows:

- (1) a recombinant silkworm is produced by using transposon named piggyBac,
- (2) it is possible to produce a protein of an isomer such as human collagen, interferon or defensin of *Oryctes rhinoceros* instead of a silk thread protein by incorporating a gene, which is expressed in a large quantities in a silk thread gland, into a silkworm,
- (3) in order to generally express the target gene in a silk thread gland, a promoter region of a gene such as sericin or fibroin that is expressed peculiarly in a silk thread gland is utilized,
- (4) fibroin is secreted by the S-S bonding of an H-chain and an L-chain in a rear silk thread gland,
- (5) when a promoter having an expression property in a silk thread gland is connected to the upstream of an L-chain gene and the target protein gene is connected to the downstream of an L-chain, the transferred gene is expressed only in the rear silk thread gland and gene products are accumulated in the middle thread gland before being spewed out to be cocoons, and therefore,
- (6) it is theoretically possible to produce, in the same manner as above-mentioned, a fibroin gene of another organism as fiber which is spewed out from a silkworm.

Claims 1-26

The subject matters of claims 1-26 do not appear to involve an inventive step in view of documents 1-6.

Document 4 describes an amino acid motif in case of manufacturing artificial fiber.

Documents 5 and 6 describe an amino acid array of a spider thread protein. Document 5 also describes an analogue of a novel spider silk protein obtained from the repeating unit of an amino acid common array.

It is publicly known to transfer a gene encoding a fusion of an H-chain or an L-chain of fibroin with a spider thread protein into a silkworm. So, it is recognized that a person skilled in the art could have easily conceived of fusing an H-chain with a gene encoding a spider thread protein by the method described in documents 1-3 and utilizing piggyBac for obtaining a silkworm, which spews out fiber for textile.

In addition, it is recognized that utilizing the amino acid array of a publicly known spider thread protein or an artificial spider thread protein making reference to an analogue as described in documents 4-6 could have been adequately performed.